REMARKS

Status of Claims

After entry of this amendment, claims 33 and 34 will be pending in this application.

Telephone Interview

Applicants kindly thank the Examiner for participating in a telephone interview with the undersigned on October 10, 2007. During the interview, the Examiner explained her rationale for denying the benefit of the filing date of the 60/101,318 provisional application ("the '318 provisional application") to the claimed invention.

Entitlement to the Priority Date of the '318 Provisional Application

Applicants respectfully request reconsideration of the finding that the '318 provisional application fails to disclose a specific, substantial and credible utility for the claimed invention.

The Examiner states that she has never disputed that the similarity between IL-7 and IL-B50 is of statistical significance and states that "[b]ased on this limited degree of similarity, one of skill in the art would reasonably conclude that the disclosed protein would probably have some effect, 'stimulatory or inhibitory', rather than no effect at all, on certain cells." The Examiner further argues that "the disclosure of the structure of the polypeptide alone and assertion that it would either inhibit or stimulate activity of certain cell types based on a limited, 28.1% similarity to another polypeptide with diverse spectrum of functions, provides for assertion of a use which is so vague that it is meaningless."

The fact that IL-7 may have a diverse spectrum of functions is irrelevant. The '318 provisional application asserts that IL-B50 is likely to have stimulatory or inhibitory effects on hematopoietic cells. Applicants respectfully submit that the asserted utility of "stimulating or inhibiting" hematopoietic cells is specific. Not all proteins can stimulate or inhibit hematopoietic cells. In fact, many (if not most) proteins are likely to have no effect on hematopoietic cells. Thus the asserted utility of IL-B50 is specific and not generally applicable to all proteins. Further, the asserted utility is substantial, and provides a real world benefit to the public due to the involvement of hematopoietic cells in immunotherapy and autoimmunity.

Applicants respectfully submit that the facts of this case can be clearly distinguished from those of *In re Fisher*, 421 F.3d 1365 (2005). In *Fischer*, the claims at issue were directed to ESTs (expressed sequence tags) of genes with no known functions. Further, all of the utilities asserted by *Fischer* were equally applicable to all ESTs (for example the use of the ESTs to identify polymorphisms, to design oligonucleotide probes or primers, and to measure mRNA expression levels). Thus, unlike Applicants, *Fischer* did not claim any utility which was specific and could distinguish the claimed ESTs from other ESTs. Moreover, *Fisher* did not present any evidence to support the asserted uses "as presently beneficial and hence practical". *Id.* at 1377. In contrast, the use of IL-B50 to stimulate or inhibit hematopoietic cells is presently beneficial as it provides a target for immunotherapy and autoimmunity.

Moreover, the utility asserted in the '318 provisional application is credible (i.e., believable based on the record or the nature of the invention). According to the MPEP, an assertion of utility is credible "unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion." *See* MPEP § 2107.02. The utility asserted in the '318 provisional application was based on the inventors' recognition of the significant sequence and structural similarity between IL-7 and IL-B50. This included the recognition that IL-B50 would bind to the alpha subunit of the IL-7 receptor along with another receptor subunit ('318 provisional application, page 49, lines 25-28). Based on these similarities, the inventors recognized that IL-B50 and IL-7 would share similar functions. As we previously submitted, the significance of the disclosed similarity between IL-7 and IL-B50 could have been confirmed by a person of skill in the art at the time the provisional application was filed. Further, a person of skill in the art at the time the '318 provisional application was filed would have understood that the areas wherein the homology between IL-7 and IL-B50 are highest correspond to the regions in IL-7 that are important for binding other proteins, including IL-7R. *See* Sali Declaration, filed June 19, 2007, ¶11. Thus, as confirmed by Dr. Sali, a person of skill in the art at the time the '318 provisional application was filed would have believed Applicants' statements regarding the similarity between IL-B50 and IL-7 and would have found the asserted utility of stimulating or inhibiting hematopoietic cells to be credible.

Applicants previously submitted post-filing publications which confirm that IL-B50 stimulate the proliferation of B cells and T cells. Applicants are submitting herewith a publication by Osborn et al., *Blood* 103(3):843-851 (2004) (Exhibit A; cited on the IDS filed on June 19, 2007), which shows that IL-B50 can *stimulate or inhibit* hematopoietic cells as asserted in the '318 provisional application. In particular, the publication by Osborn et al. shows that TSLP transgenic mice had *negative regulatory effects of lymphopoiesis* (i.e., the generation of lymphoid cells, such as B cells and T cells) *and positive regulatory effects on myelopoiesis* (i.e., the generation of myeloid cells, such as macrophages, dendritic cells, granulocytes). (Lymphoid and myeloid cells are hematopoietic cells.) Thus, post-filing evidence demonstrates the accuracy of the asserted utility.

The Examiner also argues that "a skilled practitioner would have to perform significant amount of further research to discover what is, if any, that particular effect that IL-B50 shares with IL-7." Applicants respectfully submit that a person of skill in the art at the time the '318 provisional application was filed could have tested the stimulatory or inhibitory effect of IL-B50 using only routine experimentation. The fact that further experimentation could be conducted does not negate the fact that the application discloses a specific and substantial utility for the claimed invention.

Applicants draw the Examiner's attention to the attached non-precedential opinion by the Board of Patent Appeals and Interferences ("the Board"): *Ex parte Hedrick*, Appeal No. 2005-1922, Application No. 09/770,528 (mailed September 22, 2005) (Exhibit B). In *Ex parte Hedrick*, the claims on appeal were directed to binding compounds (e.g., antibodies) which specifically bound to IL-1δ. The claims were rejected by the Examiner for lack of utility. The Board reversed. The specification asserted that IL-1δ "likely plays a role in modulating of local and systemic inflammatory processes" (*see Ex parte Hedrick*, page 7). The Examiner found the asserted utility to be non-specific and insubstantial, apparently based on "the lack of disclosure regarding the specific role that IL-1δ plays in inflammation", and the fact that the specification did not specify whether IL-1δ could contribute to or inhibit inflammation (*see Ex parte Hedrick*, pages 9-10). The Board found the Examiner's concerns to be unwarranted, and stated:

> Once it has been accepted that IL-1δ either contributes to or inhibits the inflammatory response, it seems that those skilled in the art would recognize the claimed binding compounds as useful. Specifically, if IL-1δ

> contributes to inflammation, those skilled in the art would recognize the claimed compounds to be useful in inhibiting inflammation. On the other hand, if IL-1δ inhibits inflammation, those skilled in the art would recognize the claimed compounds to be useful in promoting inflammation.

(*see Ex parte Hedrick*, page10). The Board also specifically found that the use of post-filing evidence demonstrating the accuracy of the asserted utility was acceptable, and noted that in the context of pharmaceutical inventions useful necessarily includes the expectation of further research and development (*see Ex parte Hedrick*, pages10-11).

Applicants respectfully submit that the facts of this case are at least as compelling as the facts in *Ex parte Hedr*ick. The '318 provisional application discloses that IL-B50 is a cytokine related to IL-7 and that it is likely to have "either stimulatory or inhibitory effects on hematopoeitic cells". (*See* '318 provisional application, page 9, lines 1-14.) It states that IL-B50 is involved in controlling the biology of physiology of mammalian cells, e.g., cells of mammalian immune system. (*See* '318 provisional application, abstract). It also states that IL-B50 may also be useful in the treatment of immune disorders, *e.g.*, T cell immune deficiencies, chronic inflammation, or tissue rejection, or in cardiovascular or neurophysioloigcal conditions. (*See* the' 318 application at page 13, lines 1-4.) As discussed above, post-filing evidence confirms the accuracy of the asserted utility. Therefore, a finding of utility is warranted in this case

In view of the arguments presented above and in previously submitted responses, Applicants respectfully request that the pending claim be awarded the priority date of the '318 provisional application.

Rejection Under 35 U.S.C. § 102(e)

Claim 33 stands rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,555,520 ("the '520 patent"). Applicants respectfully submit that the pending claims are entitled to the filing date of the '318 provisional application. Therefore, the '520 patent is not prior art, and this rejection should be withdrawn.

Conclusion

Applicants respectfully submit that this application is in condition for allowance.

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